

REMARKS

Claims 20, 22-24, and 26-31 were pending in the present application. By this amendment, claims 20, 22, 23 and 26 have been amended and new claims 32-34 have been added. Accordingly, claims 20, 22-24, and 26-34 are currently under consideration.

With respect to claim amendments, Applicants have not dedicated to the public or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Reconsideration of the application is respectfully requested in view of the above amendments and the following remarks. For the Examiner's convenience, Applicant's remarks are presented in the order in which they were raised in the Office Action.

A. Information Disclosure Statement

Applicants note that a Supplementary Information Disclosure Statement containing the following references are being submitted in a separate communication:

- JP 4-41421 (+ abstract) (Taisho Pharma Co Ltd, Published 1992)
- Komada et al, Journal of Pharmaceutical Sciences, vol. 83, No. 6, June 1994
- Okumura et al, International Journal of Pharmaceutics, 88 (1982), 63-73
- Joanne Broadhead, Doctor of Philosophy Dissertation, University of Rhode Island, 1993
- WO 92/06704 (AutoImmune, Inc. Published 30 April 1992)

B. Amendments to the claims and new claims

Claim 20 is amended to specify that the microparticles are water-soluble. Support for this amendment is found in the originally filed claim 1 which specified "[m]icroparticles of a

water-soluble material.” No new matter is added by this amendment and entry is respectfully requested.

Claims 22, 23 and 26 are amended to delete their dependence from cancelled claims and specify their dependence from independent claim 20. Claims 22 and 23 originally depended from now cancelled claim 21 and claim 26 originally depended from now cancelled claim 25. By the amendment filed on February 28, 2006, claim 20 was amended to include the limitations of dependent claims 21 and 25. No new matter is added by these amendments and their entry is respectfully requested.

New claims 32-34 are added. New independent claim 32 combines the limitations of pending claims 20 and 26. New claim 33 specifies that the microparticles further comprise an additive that modifies a physical property selected from the group consisting of dispersibility, elasticity and water permeability. Support for the claim is found in the specification at page 13, lines 27-29. New claim 34 specifies that the additive is a phospholipids. Support is found at page 13, line 36 of the specification.

No new matter is added by new claims 32-34. Entry of these claims is respectfully requested.

C. Amendments to the Specification

The specification is amended to recite the full continuing data of this application as required by the Office Action. No new matter is added. Entry of the amendment and withdrawal of the objection is respectfully requested.

D. Rejections under 35 U.S.C. §102(e)

Claims 20, 22-23 and 26-31 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Platz et al. (U.S. 6,509,006 B1)

(i) Applicants submit that the Office Action has not considered Applicants' argument filed February 28, 2006 that the cited reference of US Pat. No. 6,509,006 (Platz, et al.) does not constitute prior art over the present application. For the Examiner's convenience, Applicants' arguments are reiterated below.

Platz et al. (US Pat. No. 6,509,006) has a filing date of October 26, 1999 which is later than the June 7, 1995 filing date of U.S. App. Ser. No. 08/487,420 (issued as US Pat. No. 5,993,805) of which the present application is a continuation.

Further, Platz et al. (US Pat. No. 6,509,006) is a *continuation-in-part* of: Ser. No. 08/417,507, filed Apr. 4, 1995, now abandoned; and a *continuation* of the following U.S. patent applications: Ser. No. 08/383,475, filed Feb. 1, 1995; Ser. No. 08/313,707, filed Sep. 27, 1994; Ser. No. 08/309,691, filed Sep. 21, 1994; Ser. No. 08/246,034, filed May 18, 1994; Ser. No. 08/232,849, filed Apr. 25, 1994 (issued as US Pat. No. 5,607,915); Ser. No. 08/044,358, filed Apr. 7, 1993; and a *continuation-in-part* of: Ser. No. 07/910,048, filed Jul. 8, 1992 (issued as US Pat. No. 5,458,135; "the '135 patent"). Thus the earliest priority date Platz can be entitled to is **Jul. 8, 1992**.

The present application (Ser. No. 10/804,679) is a *continuation* of US Ser. No. 09/382,561, filed Aug. 25, 1999 (issued as US Pat. No. 6,709,650), which is a *continuation* of 08/487,420, filed June 7, 1995 (issued as US Pat. No. 5,993,805), which is a *continuation-in-part* of: US Ser. No. 07/956,875, filed March 15, 1993 (issued as US Pat. No. 5,518,709), which is a § 371 U.S. Application from PCT/GB92/00643 filed **April 10, 1992** based on the UK Application Ser. No. 9107628.1 filed **April 10, 1991**.

Applicants note that the claimed subject matter of the present application was disclosed in US Ser. No. 07/956,875, filed March 15, 1993 (US Pat. No. 5,518,709) which claims priority to UK Application Ser. No. 9107628.1, filed April 10, 1991. (The '709 patent has the same specification as the corresponding PCT Application PCT/GB/00643 filed **April 10, 1992**). Support for the subject matter of the currently pending claims is found in the Specification of US Ser. No. 07/956,875 (US Pat. No. 5,518,709), including among others the abstract; 1:62 – 4:5; 4:32 – 5:17; 5:52 – 7:27; 7:53 – 60; Examples 1–7, – 10.

The earliest priority date to which Platz et al. can be entitled to is **Jul. 8, 1992** based on Ser. No. 07/910,048, whereas Applicants are entitled to earlier priority dates of PCT/GB92/00643 filed **April 10, 1992** based on the UK Application Ser. No. 9107628.1 filed **April 10, 1991**. Therefore, Platz is not "prior" art under 35 U.S.C. §102(e).

(ii) In order to distinguish Platz and solely to expedite prosecution, Applicants have further amended claim 20 to specify that the microparticles are water-soluble.

While Platz (US Pat. No. 6,509,006) itself is not prior art against the present application, the Examiner argues that the earliest priority document that Platz is entitled to, Ser. No. 07/910,048 (USPN 5,458,135; "the '135 patent"), discloses relevant material at col. 5, lines 52-59 and col. 6, lines 6-9.

The Examiner cites the Platz priority document (the '135 patent) at col. 5, lines 52-59 for teaching the delivery of medicaments and drugs such as proteins and polypeptides. The '135 patent at col. 6, lines 6-9 is cited for teaching 1-5 microns particle size.

In contrast, pending claim 20, as amended, specifies a therapeutic composition comprising *inter alia* "discrete water-soluble microparticles which comprise a water-soluble carrier and a therapeutically effective amount of therapeutic agent." (emphasis added). The microparticles according to claim 20 contain both (i) "a carrier selected from simple and complex carbohydrates" and (ii) a "therapeutic agent which is a protein, peptide or enzyme." Claim 20 does not recite microparticles that are a mixture of separate particles of carrier and therapeutic agent. The '135 patent does not teach or disclose any such microparticles.

At column 5, lines 52-59, the '135 patent merely states that medicaments may be delivered to the lung. The '135 patent does not mention water-soluble microparticles that comprise both a carrier and a therapeutic agent. The 1 to 5 micron particle size disclosed at col. 6 of the '135 patent does not cure this deficiency.

Applicants note that the '135 patent at col. 12, lines 24-32, discloses spray drying a solution containing mannitol and bovine serum albumin. However, bovine serum albumin is not a therapeutic agent. The specification, at page 17, lines 25-30, states that human serum albumin is an example of a "carrier material." Further, the experiment disclosed in cols. 16-18 of the '135 patent (or anywhere else in the '135 patent) does not disclose formation of water-soluble microparticles as specified in amended claim 20.

There is no disclosure in the '135 patent of a composition comprising water-soluble microparticles as specified in amended claim 20. Further, the '135 patent relates to an apparatus for delivery of aerosolized doses of medicaments.

As discussed above Platz may be prior art over the present application only if its priority document, the '135 patent, provides an anticipating disclosure of the pending claims. Since the '135 patent does not disclose water-soluble microparticles comprising both a water-soluble carrier and a therapeutic agent, it does not teach or suggest each and every element of the microparticles specified in claim 20, as amended. Therefore, Applicants respectfully request withdrawal of this ground for rejection under 35 USC § 102 over Platz.

The specific therapeutic agents recited in dependent claims 26 and 27 (protein selected from insulin, parathyroid hormone, alpha-1 antitrypsin and calcitonin) are not disclosed in the '135 patent. New independent claim 32 recites these specific agents in addition to the limitations of claim 20. Moreover, dependent claim 29, specifies that "the microparticles form a free-flowing powder" -- a limitation that also is not disclosed by the '135 patent.

New dependent claims 33 and 34 include an added limitation of an additive agent included in the microparticles according to claim 20.

Claims 22-24, 26-31 and 33-34 depend from claim 20. New independent claim 31 includes the limitations of claim 20. Since Platz does not anticipate claim 20, Applicants respectfully request that the rejection of claims 22-24, and 26-34 over Platz be withdrawn.

E. Claim objections

Claims 22, 23, 26 and 27 are objected to for depending in cancelled claims 21 and 25.

In response, Applicants have amended claims 22, 23 and 26 to depend from independent claim 20. Claim 20 was previously amended to include all limitations of claims 21 and 25 and therefore no new matter is added by these amendments.

The Examiner also states that claim 27 depends from claim 36. Applicants note that claim 27, as filed by preliminary amendment dated October 20, 2004, depends from claim 26 (not claim 36) and no correction is necessary.

Withdrawal of these grounds for objection is respectfully requested.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to allow this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. **03-1952** referencing docket no. 263742002802. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: January 29, 2007

Respectfully submitted,

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